Brussels, 23 September 2021

Minutes of the fifth meeting of the expert group to discuss a draft delegated act on rules for the use of veterinary medicinal products for prevention and control of certain listed diseases under Regulation (EU) 2016/429

23 September 2021, Brussels

1. Approval of the agenda

An annotated agenda was circulated prior to the meeting and approved at the beginning of the meeting.

2. Nature of the meeting

The meeting was non-public. Because of the constraints related to the COVID-19 situation, the meeting was held via Skype for business with the representatives of the competent veterinary authorities of Member States and EEA countries attending. The Chair noted the absence of the European Parliament and the Council.

3. List of points discussed

3.1. Introduction

The Commission recalled that the purpose of the meeting was to continue discussing the draft Commission Delegated Regulation supplementing Regulation (EU) 2016/429 (the 'Animal Health Law') (AHL) as regards the use of veterinary medicinal products (VMPs) to prevent and control certain listed animal diseases and in particular the use of vaccines (the draft). The Commission explained the interruption of the discussions on this draft act after the meeting held on January due to the fact that this draft deserves a thorough reflection and the heavy workload that the entry into application of the Animal Health Law (AHL) posed for both Member States and the Commission services.

A revised version of the draft was circulated prior to the meeting.

3.2. Presentation and discussion on the draft-Delegated act

Presentation

The Commission started with a presentation giving an overview of the main changes introduced in the text of draft SANTE/7144/2020 after the meeting held on 27 January 2021, with the corresponding explanations.

Part I of the draft

The Commission explained the main changes in the scope, including the complete removal of rules for category C and D diseases. This removal is possible since the rules laid down in other Delegated Regulations under the AHL provide for the necessary regulatory framework to Member States for the use of VMPs for prevention and control of those diseases. As regards category B diseases, certain restrictions for the use of certain VMPs have been maintained. With these changes, the Commission considered that concerns expressed by Member States in previous meetings as regards category B, C and D diseases have been resolved.

Some Member States intervened to support this new simplified approach.

The Commission also informed about the introduction of a specific paragraph in Article 3 for the specific use of vaccines for prevention of Newcastle disease, to align with the current routine use of such vaccines for the prevention of that disease, and to avoid any unnecessary burden.

Several Member States welcomed this new addition. In their view, vaccination against Newcastle disease (ND) needs a separate approach and vaccination against this disease outside an official programme should be possible.

The Commission also explained the changes introduced in the table set out in Annex I, in which only the prohibition to use vaccines for prevention and control of Rinderpest has been maintained together with special rules for the use of certain diagnostic immunological VMPs.

Part II of the draft

Title I

The Commission explained that Part II of the draft-Delegated act, which focuses on the use of vaccines for the prevention and control of category A diseases in terrestrial animals, has been further improved and simplified. In particular, as regards vaccination strategies and the requirements for their implementation.

The Commission invited Member States to reflect whether the general rules provided for in Title I of Part II of the draft-Delegated act should also cover aquatic animals, regardless of the fact that there are currently no available vaccines for category A diseases of fish.

Title II

- **General part and annexes on foot and mouth disease and infection with lumpy skin disease**

This title provides for the disease-specific rules on vaccination for each category A disease. The Commission explained the specific rules for the use of vaccines for prevention and control of foot and mouth disease and infection with lumpy skin disease.

There were no comments from Member States in this regard.

- **Highly pathogenic avian influenza and Newcastle disease**

The discussion focused on the possible approach for the rules on the use of vaccines for prevention and control of highly pathogenic avian influenza (HPAI) and ND. In this sense, the Commission gave a presentation in which it explained the approach proposed for the specific rules in relation to vaccination for the two diseases.

For both diseases the specific rules proposed by the Commission are mirroring the old rules, as they were laid down by Directives 2005/94/EU and 92/66/EC, awaiting new scientific knowledge. On that note, the Commission informed that it will request a new scientific opinion to EFSA on vaccination against HPAI.

For ND, the Commission asked Member States to explain the type of situations when the use of vaccines for ND as preventive purposes should not be covered by all the conditions laid down in the regulation.

Some Member States provided with information in regard to ND. The majority of Member States indicated that they will revert to the Commission in writing with their views on both diseases.

4. Miscellaneous.

4.1. Conclusions

The Commission thanked Member States for their input and invited them to provide their written feedback by 6 October 2021.

5. Next steps

The Commission will use the outcomes of the discussion and the opinions obtained during this expert group meeting and the requested written comments to develop a revised version of the draft-Delegated act, which will include disease-specific rules for all category A diseases.

6. Next meeting

The Commission plans to organise a sixth meeting of the Expert Group at the end of October 2021.